IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Manne Satyanarayana REDDY et al. Art Unit: 1626

Application No.: 10/516,897 Examiner: R. H. Havlin

Filed: July 5, 2005

For: 3-[2'-(DIMETHYLAMINO)ETHYL]-N-METHYL-1H-INDOLE-5-METHANE SULFONAMIDE AND THE SUCCINATE THEREOF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

RESPONSE

This is submitted in response to the Office Action that was mailed on December 23, 2008 for the subject application. Since the submission is not being made within the period that was set, a petition to extend the period is also being submitted.

The Office Action imposed a restriction requirement, and identified the following groups of claims as constituting multiple inventions:

I. Claims 1-7 and 29, relating to crystalline Form-I of sumatriptan succinate.

II. Claims 13-20, 30, and 42, relating to crystalline Form-II of sumatriptan succinate.

III. Claims 8-12, relating to a process for making crystalline Form-I of sumatriptan succinate.

IV. Claims 21-24, relating to a process for making crystalline Form-II of sumatriptan succinate.

V. Claims 27-28, relating to a process for preparing sumatriptan.

VI. Claims 36-41 and 43, relating to crystalline sumatriptan.

VII. Claim 44, relating to the treatment of migraine with crystalline Form-I of sumatriptan succinate.

VIII. Claim 45, relating to the treatment of migraine with crystalline Form-II of sumatriptan succinate.

IX. Claim 46, relating to the treatment of migraine with crystalline sumatriptan.

X. Claim 47, relating to crystalline sumatriptan prepared by the process of claim 27.

Restriction was asserted as being proper because the inventions are considered to be independent or distinct, and would impose a serious search and examination burden.

Applicants respectfully traverse this requirement.

Initially, Applicants note that all of the pending claims have already been searched and examined. In fact, there have been two previous rejections of these same claims (a non-final rejection on April 17, 2007 and a final rejection on December 12, 2007), and the claims presently are not under any rejection. Presumably, the prior art was thoroughly searched and fully considered, prior to providing the rejections to the Applicants, and no additional searching is now needed. There is no apparent valid purpose that would be served by imposing a restriction requirement at this late stage of the examination process.

Applicants also point out that each of the pending claims relates to one of only two possible chemical compounds: the drug compound known by its adopted name "sumatriptan" and its salt with succinic acid. A search relating to one of these compounds necessarily involves the same publications as would be encountered in a search relating to the other compound.

Further, M.P.E.P. § 1893.03(d) states: "Examiners are reminded that unity of invention (not restriction practice pursuant to 37 CFR 1.141-1.146) is applicable … in national stage applications submitted under 35 U.S.C. 371." Since the present application is a United States national stage application from International Application No. PCT/US03/19004, it is not subject to restriction using the criteria discussed in the Office Action.

The appropriate standards for determining unity of invention under the Patent Cooperation Treaty are explained in M.P.E.P. § 1850, and a determination involves evaluation of whether the perceived inventions are so linked as to form a single

inventive concept. There are several considerations, including specific situational guidance such as is expressed in the following excerpt from 37 C.F.R. § 1.475:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
> (1) A product and a process specially adapted for the manufacture of said product.

This improper restriction requirement should not be maintained, upon reconsideration. However, in the event that the requirement is maintained, Applicants provisionally elect the claims of Group III (being claims 8-12) for an initial examination.

CONCLUSION

Since the restriction requirement is not in accord with applicable legal and procedural requirements, and the pending claims have all been fully examined and are not subject to any rejections, a prompt notification of allowability is now appropriate and is respectfully solicited. If any matters remain to be resolved in connection with this submission, please contact the undersigned by telephone or facsimile to expedite resolution.

Respectfully submitted,

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